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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DANIELA KLEINWAECHTER, GUENTER MODDELMOG, and ROBERTO OGNIBENE[1]

Appeal 2016-005816
Application 13/000,241
Technology Center 1600

Before JEFFREY N. FREDMAN, RICHARD J. SMITH, and RYAN H. FLAX, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a co-mixture or tablet formulation. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] According to Appellants, the real party in interest is MERCK PATENT GESELLSCHAFT MIT BESCHRANKTER HAFTUNG. (Appeal Br. 1.)

STATEMENT OF THE CASE

Claims on Appeal

Claims 1–8 and 10–16 are on appeal.[2] (Claims Appendix, Appeal Br. 21–22.) Claims 1 and 10 are illustrative and read as follows:

> 1. A co-mixture for the production of rapidly disintegrating tablets, consisting of 90 - 98 parts by weight of a sprayed mannitol and 10 - 2 parts by weight of a crosslinked sodium carboxymethylcellulose,
>
> wherein the co-mixture has a BET surface area of greater than 1.5 m^2/g,
>
> and which has been compressed at a pressing force of 20 kN, to produce tablets having hardnesses > 250N, a friability ≤ 0.14% and a disintegration time ≤ 70 seconds.
>
> 10. An active compound- and/or aroma-containing tablet formulation, comprising an active compound and/or aroma and a co-mixture
>
> consisting of 90 - 98 parts by weight of a sprayed mannitol and 10 - 2 parts by weight of a crosslinked sodium carboxymethylcellulose,
>
> wherein the co-mixture has a BET surface area of greater than 1.5 m^2/g,
>
> and wherein the active compound and/or aroma and a co-mixture have been compressed at a pressing force of 20 kN, to produce tablets having hardnesses > 250N, a friability ≤ 0.14% and a disintegration time ≤ 70 seconds.

Examiner's Rejections

1. Claims 1–8 and 10–16 stand rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as indefinite.[3] (Final Act. 3–

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[2] Claim 9 is cancelled and claims 17–19 are withdrawn. (Final Act. 3, dated June 26, 2015.)

[3] The rejection only identifies claim 1–8, but it is clear from the text of the Final Action that claims 10–16 are included.

5.)

2. Claims 1–8, 10, and 13–16 stand rejected under 35 U.S.C. § 102(b) as anticipated by Simpson,[4] as evidenced by Satomi[5] and EMPROVE® Parteck M 200.[6] (*Id.* at 5–8.)

3. Claims 1–8 and 10–16 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Norman[7] and Cahill,[8] as evidenced by Satomi and EMPROVE® Parteck M 200. (*Id.* at 9–13.)

4. Claims 1–8 and 10–16 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Suzuki[9] and Cahill, as evidenced by Satomi and EMPROVE® Parteck M 200. (*Id.* at 13–17.)

5. Claims 11 and 12 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Simpson and Grimshaw.[10] (*Id.* at 17–18.)

FINDINGS OF FACT

We adopt as our own the Examiner's findings regarding the scope and content of, and motivation to combine, the prior art. The following findings are included for emphasis and reference purposes.

FF 1. The Specification states that "the co-mixtures according to the invention are suitable for use as excipient material for active compound- and/or aroma-containing tablet formulations which have the said advantageous properties, and tablets or other pharmaceutical formulations

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[4] Simpson et al., WO 2007/060402 A1, pub. May 31, 2007 ("Simpson").
[5] Satomi et al., US 2010/0167052 A1, pub. July 1, 2010 ("Satomi").
[6] Data Sheet for EMPROVE® Parteck M 200 (Mannitol) (2012).
[7] Norman et al., US 2003/0118642 A1, pub. June 26, 2003 ("Norman").
[8] Cahill et al., US 2009/0028943 A1, pub. Jan. 29, 2009 ("Cahill"). Cahill indicates that it is the US National Stage Publication of Simpson.
[9] Suzuki et al., JP2001163770, machine translation of record ("Suzuki").
[10] Grimshaw et al., US 7,282,217 B1, issued Oct. 16, 2007 ("Grimshaw").

with or without active compound prepared from this excipient material." (Spec. 2, ll. 31–35.)

FF 2. The Specification states that Parteck M is a sprayed mannitol. (Spec. 3, l. 26.)

FF 3. The Examiner finds that Simpson teaches pharmaceutical compositions of AZD2171 (active agent) and a plastic filler with a high surface area, such as Partech M™ mannitol, and that the composition contains from 15% to 95% of the plastic filler. (Final Act. 5, citing Simpson Abstract, 7, ll. 27–27, and 17, ll. 1–2.)

FF 4. The Examiner finds that Simpson teaches an example (Example 1) with 0.63 parts by weight of AZD2171 maleate, 94.37 parts by weight of mannitol (Parteck M™), and 4 parts by weight of sodium starch glycolate as a disintegrant. (Final Act. 6, citing Simpson 37, Example 1.)

FF 5. Simpson discloses that "[s]uitable disintegrants include those known in the art of formulation, such as those listed in The Handbook of Pharmaceutical Excipients, 4th edition, eds Rowe, R. C. et al, Pharmaceutical Press, 2003. Preferred disintegrants include sodium starch glycolate, croscarmellose sodium and starch." (Simpson 18, ll. 13–16.)

FF 6. The Examiner finds that croscarmellose sodium is a crosslinked sodium carboxymethylcellulose (recited in claims 1 and 10). (Ans. 4.)

FF 7. The Examiner finds that Simpson teaches the same materials in the same amounts as claimed, and that one of ordinary skill in the art would expect that use of the same materials in the same amounts would produce the same BET surface area. (Final Act. 6.)

FF 8. The Examiner finds that Norman teaches a composition that may include a dry mixture of mannitol, in a range of about 60% to about 99.5%,

and a disintegrant, which may be selected from croscarmellose, crospovidone, or sodium starch glycolate, or mixtures thereof. (Final Act. 9, citing Norman Abstract and ¶¶ 17, 20.) The Examiner further finds that, in an embodiment of Norman, the dry mixture includes about 90% mannitol and about 10% disintegrant, that Norman teaches the addition of an active ingredient, such as a pharmaceutical or nutraceutical, and that tablets are prepared from the composition. (Final Act. 9, citing Norman ¶¶ 11, 19, 22, and 134.)

FF 9. The Examiner finds that Cahill teaches that a plastic filler with a high surface area as the principal excipient, such as Parteck M™ mannitol, has particularly advantageous properties. (Final Act. 10, citing Cahill ¶¶ 29 and 31.)

FF 10. The Examiner finds that Suzuki teaches a rapidly disintegrating tablet, including excipients such as mannitol and a disintegrant such as croscarmellose sodium, and that an active compound (medicinal ingredient) may be included in the tablet. (Final Act. 13–14, citing Suzuki Abstract and ¶¶ 1, 12, 14, and 19.)

DISCUSSION

Except as otherwise indicated, we adopt the Examiner's findings, analysis, and conclusions as our own, as set forth in the Final Action (Final Act. 3–24) and Answer (Ans. 2–12).

Rejection No. 1

Issue

Whether a preponderance of evidence of record supports the Examiner's indefmiteness rejection under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph.

Analysis

The Examiner rejects claims 1 and 10 for being indefinite, and claims 2–8 and 11–16, respectively, for depending on an indefinite base claim. (Final Act. 4–5.)

Claim 1

The Examiner rejects claim 1 because "[i]t is not clear how the claim can be drawn to a co-mixture with an intended use of the production of rapidly disintegrating tablets, but requires the formation of a tablet." (*Id.* at 4.) Appellants argue that "there is no conflict between the preamble of the claims and the body" (Appeal Br. 3), and that "the claim is clearly and simply directed to a co-mixture that has been pressed into a tablet," i.e., "a tableted co-mixture" (Reply Br. 1–2).

We find that the Examiner has the better position. A claim is indefinite when it contains language that is "ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention." *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014). Here, the claim recites a "co-mixture," which the Specification indicates is an excipient material for a tablet, not a tablet. (FF 1.) Moreover, Applicants' arguments to the contrary reflect the vague and ambiguous nature of claim 1.

Claim 10

The Examiner concludes that claim 10 is indefinite because

> It is not clear if the limitation of "wherein the co-mixture has a BET surface area of greater than 1.5 [m^2/g]" refers to the co-mixture after it has been compressed into the tablet or before. Further, the preamble of the claim is drawn to a "tablet formulation". It is not clear if the claim is actually drawn to a tablet or just a formulation for producing a tablet.

(Final Act. 4–5.)

Appellants argue that "[t]he claim clearly describes the relevant BET surface area as that of the co-mixture," and reassert the arguments advanced in connection with claim 1 (i.e., that the claim is to a tablet). (Appeal Br. 4.)

We find that Appellants have the better position. Unlike claim 1, claim 10 distinguishes the co-mixture from the tablet formulation (i.e. the co-mixture is a component of the tablet formulation) and indicates that the BET surface area is referring to the co-mixture (before being formed into a tablet). (*See* FF 1.) Moreover, unlike the term "co-mixture," the Specification refers to "tablets or other pharmaceutical formulations" (*id.*), thereby reasonably indicating that a tablet formulation includes a tablet.

Conclusion

A preponderance of evidence supports the Examiner's rejection of claim 1 under 35 U.S.C. § 112 as indefinite. Claims 2–8 fall with claim 1.

A preponderance of evidence fails to support the Examiner's rejection of claim 10 under 35 U.S.C. § 112 as indefinite. Claims 11–16 stand with claim 10.

Rejection No. 2

Issue

Whether a preponderance of evidence of record supports the Examiner's rejection under 35 U.S.C. § 102(b).

Analysis

Claim 1

Claim 1 is interpreted as a co-mixture "consisting of 90 - 98 parts by weight of a sprayed mannitol and 10 - 2 parts by weight of a crosslinked sodium carboxymethylcellulose." (Appeal Br. 21.) "'[C]losed' transition

phrases such as 'consisting of' are understood to exclude any elements, steps, or ingredients not specified in the claim." *AFG Indus., Inc. v. Cardinal IG Co., Inc.,* 239 F.3d 1239, 1245 (Fed. Cir. 2001). Accordingly, claim 1 recites a co-mixture of only those components.

Appellants argue that Simpson "emphasizes inclusion of components which are excluded from the claims." (Appeal Br. 6.) We are persuaded by Appellants' arguments, at least because Simpson's tablet includes components such as AZD2171 maleate in addition to the claimed components. (FF 4; Simpson Example 1.) Accordingly, the rejection of claim 1 for anticipation is reversed.

Claim 10

Claim 10 is interpreted as a drug formulation *comprising* an active compound and/or aroma and a co-mixture. (Appeal Br. 21–22.) Thus, unlike claim 1, use of the open-ended term "comprising" permits ingredients or components, in addition to the recited active compound and/or aroma and co-mixture, to be included in the drug formulation without falling outside the scope of the claim. *See In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004) ("The reasonable interpretation of the claims containing both of the terms 'comprising' and 'consists' is that the term 'consists' limits the 'said portion' language . . . but the earlier term 'comprising' means that the claim can include that portion plus other [components].") . Appellants contest the anticipation finding with several arguments.[11]

[11] Appellants incorporate their arguments regarding claim 1 into their arguments for claim 10. (Appeal Br. 8.)

Product by Process Limitation

Appellants argue that the claim phrase "and wherein the active compound and/or aroma and a co-mixture have been compressed at a pressing force of 20 kN, to produce tablets having hardnesses > 250N, a friability ≤ 0.14% and a disintegration time ≤ 70 seconds" is not disclosed by Simpson. (Appeal Br. 5–6.) Appellants also argue that claim 10 requires "that the tablet be formed under specific conditions" which results in "real structural limitations." (*Id.* at 5.)

We are not persuaded. It is well settled that "[t]he patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citations omitted). Moreover, "[w]here a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product." *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983) (affirming rejections under Sections 102 or 103).

Claim 10 recites a product (tablet formulation or tablet), and the issue is whether Simpson discloses that product so as to anticipate claim 10. Here, we find that the Examiner has set forth a sound basis for concluding that Simpsons' tablet and Appellants' claimed tablet are the same, and Appellants have not identified persuasive evidence to the contrary. In particular, Appellants have not shown that Simpson's tablet does not have

the same properties as the tablet claimed.[12] *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (holding that "when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.").

Additional Components

Appellants argue that Simpson discloses additional components, such as the AZD2171 active ingredient, that are excluded from claim 10. (Appeal Br. 6–7.) We are not persuaded because claim 10 uses the open-ended transitional term "comprising," thus permitting additional components (*e.g.,* AZD2171) within the scope of the claimed drug formulation. *See* discussion, *supra*.

Number of Disintegrants

Appellants contest the Examiner's finding that Simpson "teaches that preferred disintegrants include sodium starch glycolate, croscarmellose sodium (a crosslinked sodium carboxymethylcellulose), and starch," and that "[t]he number of species recited is small and thus easily envisioned." (Appeal Br. 7, citing Final Act. 6.) In particular, Appellants argue that, based on the number of known disintegrants listed in The Handbook of Pharmaceutical Excipients (FF 5), the number of species recited in Simpson "is **not** small and not immediately envisioned." (Appeal Br. 7.)

We are not persuaded. Our reviewing court's decision in *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC,* 683 F.3d 1356 (Fed. Cir.

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[12] While we do not agree with Appellants' characterization of the *properties* of the claimed tablet (i.e., after the components "have been compressed at a pressing force of 20 kN") as *structural limitations*, the analysis is the same, and Appellants have not shown that Simpsons' tablet does not have the same properties or structural limitations as claimed.

2012), is pertinent to the present facts. In *Wrigley*, the court affirmed an anticipation finding where the prior art reference disclosed the combination of menthol with WS–23 (a cooling agent), which the prior art reference identified "as one of three 'particularly preferred' cooling agents." *Id.* at 1361–62. In a similar fashion, Simpson specifically discloses croscarmellose sodium (a crosslinked sodium carboxymethylcellulose) as one of three "[p]referred disintegrants" to be used with Parteck M mannitol. (FF 5.) Accordingly, we find that "the combination of [Parteck M mannitol] and [crosslinked sodium carboxymethylcellulose] would [] be immediately apparent to one of ordinary skill in the art." *See Wrigley*, 683 F.3d at 1361.

Conclusion

A preponderance of evidence of record fails to support the Examiner's rejection of claim 1 under 35 U.S.C. § 102(b). Claims 2–8 stand with claim 1.

A preponderance of evidence of record supports the Examiner's rejection of claim 10 under 35 U.S.C. § 102(b). Claims 13–16 were not argued separately and fall with claim 10.

Issue

Whether a preponderance of evidence of record supports the Examiner's rejections under 35 U.S.C. § 103(a).

Analysis

Appellants contest the three obviousness rejections by arguing unexpected results, which we weigh with the additional arguments advanced by Appellants. We limit our consideration to claims 1 and 10 because the remaining rejected claims were not argued separately. Moreover, because

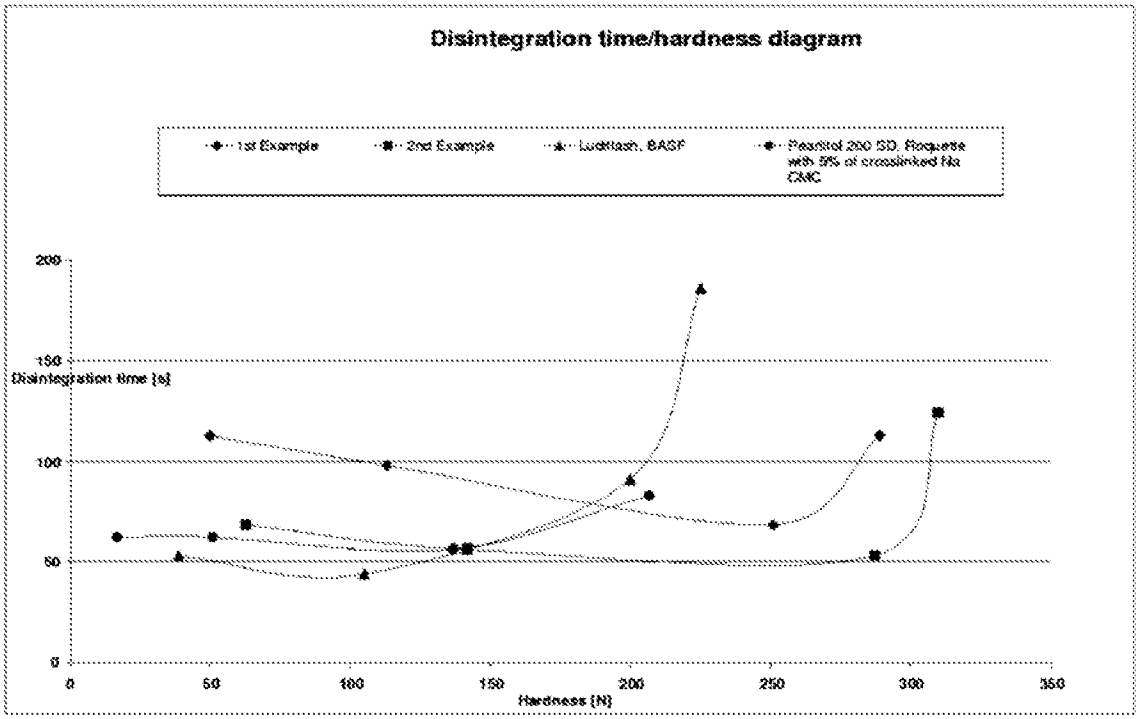
Appellants rely on the same arguments for both claims 1 and 10, we address those arguments together.

Unexpected Results

Appellants argue that they have provided "evidence of unexpected results over the examples of Cahill," and refer to Fig. 1 from the Specification, which is reproduced below. (Appeal Br. 17–18; Reply Br. 10–11.) According to the Specification, the first and second examples in Fig. 1 are "according to the invention" and consist of "a mixture of 90-98 parts of Parteck M with 10 to 2 parts of a superdisintegrant, preferably with crosslinked Na CMC."[13] (Spec. 6, ll. 20–22.) The third sample is Ludiflash, BASF, and consists of mannitol/crospovidone/polyvinyl acetate/povidone. (Spec. 13–14.) The fourth sample is Pearlitol 200 SD (a mannitol) and 5% crosslinked Na CMC. (*Id.*) We understand from the Specification that the four data points for each sample in Fig. 1 reflect four compression forces (5,

[13] The Specification indicates that the ratio of mannitol to disintegrant in examples 1 and 2 is 95:5. (Spec. 10, ll. 30–32.) We understand that Na CMC refers to sodium carboxymethylcellulose.

10, 20 and 30 kN). (*Id.*)



The above chart (Spec. Fig. 1) reflects disintegration time(s) on the Y axis and hardness (N) on the X axis for four samples.

Based on the data reflected in Fig. 1, Appellants argue that examples 1 and 2 achieved high hardness values while maintaining good (i.e. low) disintegration times. (Appeal Br. 18.) In contrast, Appellants argue that "[f]or the same compressive forces, the comparative examples did not achieve comparably high hardness values, and the disintegration times started increasing well before higher [hardness] values were achieved." (*Id.*)

"To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014).

Here, the closest prior art is Cahill Example 1,[14] as acknowledged by Appellants (Appeal Br. 11), but it is not one of the samples compared by Appellants. Moreover, as explained by the Examiner, the results do not appear to be unexpected given Cahill's teaching of "improved compression properties in terms of hardness . . . whilst still maintaining good dissolution and disintegration properties." (Cahill ¶ 34; *see also* Ans. 9–11.)

We note Appellants' contention in the Reply Brief that the Examiner's Answer "misinterprets the data in the submitted chart and [the Examiner] improperly refuses to consider it as evidence of unexpected results." (Reply Br. 11.) Moreover, Appellants contend that they have been "unfairly and improperly denied" an opportunity to respond to the Examiner's treatment of the unexpected results in the Answer. (*Id.*) However, Appellants had the opportunity to respond (and did respond) in the Reply Brief. (Reply Br. 10–11.) Furthermore, we have fully considered the Fig. 1 data and Appellants' contentions regarding unexpected results without relying on the Examiner's understanding of that data, and even if we accept Appellants' interpretation of that data, we are not persuaded that it overcomes the fundamental deficiencies addressed above.

Rejection No. 3

The Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize sprayed mannitol as taught by Cahill [] as the mannitol of Norman," and that one "would have been motivated to do so with a reasonable expectation of success" because Cahill teaches that a plastic filler with a high surface area

[14] Cahill Example 1 corresponds to Simpson Example 1. (*See* Cahill ¶ 288 and Simpson 37.)

as the principal excipient, such as Partech M™ mannitol, has particularly advantages properties. (Ans. 10; FF 8 and 9.)

We note at the outset that Appellants separately challenge Norman, Cahill, and Satomi.[15] However, Appellants are reminded that one cannot show nonobviousness by attacking references individually where the Examiner bases the rejection on a combination of references. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (citing *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)).

Norman

Appellants argue that Norman teaches away from the claimed invention. (Appeal Br. 8–9.) In particular, Appellants argue that Norman teaches embodiments where the dry mixture is combined with other components (thus distinguishable by the preamble transition phrase "consisting of" in claim 1), including "another DC-mannitol," and that Norman fails to teach an objective measure of tablet disintegration such that a skilled artisan would not rely on the disintegration times of Norman. (*Id.*)

We are not persuaded that Norman teaches away because Appellants' arguments do not persuasively show that Norman criticizes, discredits, or otherwise discourages the claimed invention. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or

[15] Satomi was cited in connection with the rejections of claims 6 and 7 as evidence that Partech M™ 200 has a mean particle diameter of 91 μm. (Ans. 12.) Because claims 6 and 7 were not argued separately, we do not further address Satomi.

otherwise discourage the solution claimed"). Moreover, we are not persuaded that Norman does not teach or suggest a dry mixture "consisting of" mannitol and disintegrant. (*See* Norman ¶ 22: "[i]n another embodiment . . . the method includes diluting the resulting composition with *a dry mixture of mannitol and a disintegrant*" (emphasis added).) To the extent that argument is also advanced in connection with claim 10, it is also unpersuasive because the claimed drug formulation includes components in addition to the co-mixture. *See* discussion, *supra*. In addition, the disintegration time argument relates to the property resulting from the product by process limitation, and is persuasively addressed by the Examiner.[16] (Final Act. 11.)

Cahill

Appellants advance several arguments regarding Cahill including, for example, that inherency of BET based on Cahill is inappropriate[17] and that the Examiner should have applied a "reference composition" analysis with respect to Cahill (arguing that the compositions of Cahill "would have failed to lead to the presently claimed co-mixtures"). (Appeal Br. 10–16.)

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[16] Appellants continue to assert in the Reply Brief that hardness, friability, and disintegration time are not product by process limitations (Reply Br. 6), notwithstanding their own test results showing that hardness and disintegration time are a function of compression force. *See* discussion of Spec. Fig. 1, *supra*.

[17] Contrary to Appellants contention (Appeal Br. 11), an inherency analysis may be appropriate in an obvious analysis. *See Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194–96 (Fed. Cir. 2014) (discussing inherency in the obviousness context). Moreover, pointing to the BET for a different mannitol (Appeal Br. 12) does not overcome the Examiner's finding of inherency. (Ans. 10–11.)

We are not persuaded. The Examiner's obviousness conclusion was based on Cahill's teaching of sprayed mannitol (Parteck M™ mannitol), and Appellants' arguments regarding Cahill do not explain why it would not have been obvious to utilize sprayed mannitol, as taught by Cahill, as the mannitol in Norman. (Ans. 10; FF 8 and 9.) That is, Appellants' arguments regarding Cahill do not persuade us of any error by the Examiner in either (1) an underlying finding of fact upon which the conclusion of obviousness was based, or (2) the reasoning used to reach that conclusion. *See Ex Parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential).

Rejection No. 4

The Examiner concluded that it would have been obvious to utilize sprayed mannitol as taught by Cahill as the mannitol of Suzuki. (Final Act. 13–15.) Appellants argue that Suzuki teaches away because it teaches Parteck M200 as a negative example. (Appeal Br. 19.) According to Appellants, "Parteck M200 is listed as a comparative example which has a different morphology than that of the claims, resulting in a low oil absorption and poorer compressibility." (*Id.*) While we agree with the Examiner that Cahill (not Suzuki) is relied upon for use of a sprayed mannitol (Ans. 11), we also note that the mere fact that Parteck M200 mannitol may be described as somewhat inferior does not constitute a teaching away. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Appellants also argue that Suzuki fails to teach the use of a disintegrant and provides no teaching regarding disintegration times of the tablets. (Appeal Br. 19.) We are not persuaded because Suzuki does teach a disintegrant (FF 10), and because the disintegration times are persuasively addressed by the Examiner with respect to the product by process limitation

(Ans. 11–12; *see also* discussion, *supra*.). Appellants also argue that Suzuki requires components that are excluded from the claims. (Appeal Br. 19.) We are not persuaded because, as to claim 1, Suzuki teaches and suggests a product consisting of a single mannitol and a single disintegrant (FF 10), and the fact that Suzuki discloses other combinations "does not render any particular formulation less obvious." *See Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). Appellants' argument is also unpersuasive as to claim 10 because the claim permits ingredients or components in addition to the co-mixture to be included in the drug formulation without falling outside the scope of the claim. *See* discussion, *supra*. Appellants otherwise rely on the same arguments and unexpected results contentions addressed above.

Rejection No. 5

Appellants state that the rejection of claims 11 and 12 stand or fall based on claim 10, on which they depend. (Appeal Br. 20.) The arguments and responses to the rejections of claim 10 are addressed above, and claims 11 and 12 fall with claim 10.

Conclusions of Law

Based on the record before us, including Appellants arguments and evidence, we conclude that the Examiner has established a prima facie case of obviousness with respect to Rejection Nos. 3, 4, and 5, and that the evidence of unexpected results is insufficient to overcome or rebut the respective prima facie cases of obviousness. Accordingly, we conclude as follows:

Rejection No. 3: A preponderance of evidence of record supports the Examiner's rejection of claims 1 and 10 under 35 U.S.C. § 103(a). Claims

2–8 and 11–16 were not argued separately and fall with claims 1 and 10, respectively.

Rejection No. 4: A preponderance of evidence of record supports the Examiner's rejection of claims 1 and 10 under 35 U.S.C. § 103(a). Claims 2–8 and 11–16 were not argued separately and fall with claims 1 and 10, respectively.

Rejection No. 5: A preponderance of evidence of record supports the Examiner's rejection of claims 11 and 12 under 35 U.S.C. § 103(a).

SUMMARY

We AFFIRM:

the rejection of claims 1–8 under 35 U.S.C. § 112 as indefinite;

the rejection of claims 10 and 13–16 under 35 U.S.C. § 102(b);

the rejections of claims 1–8 and 10–16 under 35 U.S.C. § 103(a) (Rejection Nos. 3 and 4); and

the rejection of claims 11 and 12 under 35 U.S.C. § 103(a).

We REVERSE:

the rejection of claims 10–16 under 35 U.S.C. § 112 as indefinite; and

the rejection of claims 1–8 under 35 U.S.C. § 102(b).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED